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APPLICATION FOR UNITED STATES LETTERS PATENT

for

**TOOL FOR ADJUSTING AN IMPLANTABLE  
ADJUSTABLE FLUID FLOW CONTROL VALVE**

by

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# TOOL FOR ADJUSTING AN IMPLANTABLE ADJUSTABLE FLUID FLOW CONTROL VALVE

## BACKGROUND OF THE INVENTION

### 1. Field of the Invention.

This invention relates generally to surgically implanted physiological shunt systems and related flow control devices. More particularly, the present invention relates to a position indicator and adjustment tool for such shunt systems having variable pressure settings for the one-way flow control valves controlling the flow of Cerebral Spinal Fluid (CSF) out of a brain ventricle and preventing backflow of fluid into the brain ventricle.

### 2. Description of Related Art

A typical adult has a total of about 120 - 150 cc of CSF with about 40 cc in ventricles in the brain. A typical adult also produces about 400 - 500 cc/day of CSF, all of which is reabsorbed into the blood stream on a continuous basis.

Sometimes, the brain produces excess CSF. One common cause of the excess production of CSF is hydrocephalus. Hydrocephalus is a condition of excessive accumulation of CSF in the ventricles or brain tissue. Hydrocephalus can result from genetic conditions or from trauma to the brain.

Excessive accumulation of CSF, due to hydrocephalus or other causes, manifests itself as increased pressure within the brain. Whatever the cause, over time, this increased CSF pressure causes damage to the brain tissue. It has been found that relieving the CSF

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33 An example of a fluid control device is shown in US Patent No. 5,637,083 issued to  
34 William J. Bertrand and David A. Watson on June 10, 1997 entitled "Implantable  
35 Adjustable Fluid Flow Control Valve", the teaching of which is incorporated herein in its  
36 entirety by reference. The valve of the '083 patent is shown in Figures 1 - 3 generally  
37 labeled 10 (20). (Reference numbers in parentheses correspond to the reference numbers in  
38 the '083 patent. After the corresponding reference number to the '083 patent has been  
39 given once, no further reference to the '083 will be given although the connection to the  
40 '083 patent is intended to be implied throughout this description.) The valve 10 includes a  
41 an inlet connector 12 (22) and an outlet connector 14 (24). A elastomeric casing 16 (30)  
42 covers the inner workings of the valve 10. A dome 18 (60) extends upward from the

43 elastomeric casing 16. Fluid flows through the valve 10 in the direction indicated by the  
44 arrow "A".

45 Valve 10 includes a mechanism to control fluid flow through the valve 10. The  
46 mechanism includes a magnet 20 (120) embedded within a base 22 (122). Rotating the  
47 base 22 changes the internal configuration of the mechanism. Changing the internal  
48 configuration of the mechanism produces a variety of pressure or flow characteristics for the  
49 valve. The base 22 may be rotated by magnetically coupling an external magnet 24 (140) to  
50 the valve's magnet 20 and rotating the external magnet 24. Because magnet 20 is coupled  
51 to the external magnet 24, when magnet 24 rotates, magnet 20 also rotates. As magnet 20  
52 rotates, base 22 rotates and the internal configuration of the mechanism changes as  
53 described in detail in the '083 patent. As the internal configuration of the valve 10 changes,  
54 the pressure/flow characteristics of the valve 10 change.

55 In use, the valve 10 is subcutaneously placed on the patient's skull. The catheter  
56 going to the patient's ventricle is attached to inlet connector 12. The catheter going to the  
57 patient's peritoneal cavity or vascular system is attached to outlet connector 14. In this  
58 way, a direction of flow is established from the inlet connector 12 through the valve 10 to  
59 the outlet connector 14. As stated above and described in detail in the '083 patent, changing  
60 the internal configuration of the mechanism by coupling the external magnet to the internal  
61 magnet and rotating the base produces a variety of pressure or flow characteristics through  
62 the valve 10.

63 A problem with current adjustable valves, such as the one described in the '083  
64 patent is that once implanted, it is difficult to determine the setting of the valve. Further, it

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65 is difficult to adjust the setting of the valve. With some adjustable valves, x-ray images are  
66 used to determine the current state or post adjustment state of the valve.

## 67 SUMMARY OF THE INVENTION

68 Tools for determining and adjusting the setting of an adjustable valve are disclosed.  
69 These tools allow a medical professional to locate and non-invasively determine the setting  
70 of an implanted valve. After the valve has been located and the setting of the valve  
71 determined, the valve may be re-adjusted non-invasively.

72           There are three tools: a locator tool, an indicator tool and an adjustment tool. The  
73 locator tool allows the physician to locate the adjustable valve of interest and align the  
74 locator tool with a specific orientation of the valve. The indicator tool indicates the current  
75 setting of the adjustable valve and confirms new settings of the valve after the new settings  
76 have been implemented. The adjustment tool interacts magnetically with the implanted  
77 adjustable valve to couple with a movable internal element to change the setting of the  
78 valve. The indicator tool and the adjustment tool physically cooperate with the locator tool  
79 to accomplish the respective functions of the tools.

80 In this invention a hand held indicator tool allows instant determination of the  
81 device setting with no requirement for using x-rays. This is accomplished in the present  
82 invention by providing a locator tool with an opening that allows tactile determination of  
83 the implanted valve's position and orientation. In the preferred embodiment, the indicator  
84 tool in this invention is keyed to the locator tool so that it can only be inserted in a correct  
85 orientation with respect to the locator tool that has previously been aligned with the valve.

86 The “keyed” relationship minimizes the possibility of erroneous readings of the valve  
87 setting.

88 In the current invention, the adjuster tool is inserted into the locator tool. The  
89 adjustment tool couples an external magnetic field to the magnet of the valve to switch the  
90 valve through a variety of pressure/flow characteristics. The adjuster tool rotates through a  
91 series of “detents” corresponding with setting positions on the valve. As the adjuster tool  
92 rotates, the user feels a click when the adjuster tool is aligned with a position of the valve as  
93 a positive tactile indication the user that a setting position has been reached. In the current  
94 invention, mechanical stops in the tool mirror mechanical stops inside the implanted valve  
95 at the range limit of rotating base of the valve. This helps prevent the user from improperly  
96 adjusting the valve.

97 Other features and advantages of the present invention will become apparent from  
98 the description of the invention herein and more particularly with reference to the drawings  
99 and the following detailed description. Throughout this disclosure, like elements, wherever  
100 named, are referred to with like reference numbers.

## 101 BRIEF DESCRIPTION OF THE DRAWINGS

102 FIG. 1 is a perspective view of an adjustable flow control valve.

103 FIG. 2 is a side cross-sectional view of the valve of Figure 1.

FIGS. 3A - 3E are top x-ray views of the valve of FIG. 1 with the magnet in a variety of orientations corresponding to varying levels of pressure/flow through the valve.

106 FIG. 4 is a perspective view of the locator tool of the present invention.

127 FIG. 19.

FIG. 21 is a perspective view of the adjustment tool of FIG. 14 being moved into contact with the locator tool of FIG. 19.

FIG. 22 is a top view of the adjustment tool of FIG. 21 in place in the locator tool of FIG. 19.

#### DETAILED DESCRIPTION OF THE INVENTION

The invention comprises three tools, a locator tool 26, an indicator tool 28 and an adjustment tool 30. Although these tools are intended to be used cooperatively in a sequential way, it is clear and within the scope of the invention that they may also be used individually are in paired relationships as will be explained hereafter.

The locator tool is shown in Figures 4 - 7 generally labeled 26. Locator tool 26 allows the physician to locate the adjustable valve 10 of interest and align the locator tool 26 with a specific orientation of the valve 10.

Locator tool 26 has a substantially planar deck 32 and a substantially cylindrical tube 34. The outer edge 36 of deck 32 is attached to the inner surface 38 of tube 34. Tube 34 has an inner diameter "D". Tube 34 has an upper surface 40. Deck 32 has a locator central axis 42. Deck 32 has a locator central opening 44 extending entirely therethrough. In the preferred embodiment, locator central axis 42 extends through a portion of locator central opening 44. In addition, locator central opening 44 has a shape as will be described below such that it allows an orientation to be ascribed to it. Deck 32 also has an arrow 46 or other means for pointing out the preferred direction of orientation of the locator tool 26.

Tube 34 preferably has a slot 48 on its inner surface 38 that extends into the material of tube 34 from the upper surface 40 downward at substantially a right angle to the plane of



150 deck 32. Slot 48 is intended to interact with the indicator tool 28 as will be described  
151 hereafter.

152 In the preferred embodiment, as seen in FIG. 6, tube 34 has a tab 50 that extends as  
153 part of "wall" of tube 34. Tab 50 is formed between two side slots 52 and a bottom slot 54  
154 that extend entirely through the material of tube 34. Tab 50 preferably extends along tube  
155 34 in a direction substantially perpendicular to the plane of deck 32.

156 A protrusion 56 extends inwardly from the bottom of tab 50 into the central portion  
157 of tube 34. Because tab 50 is attached to the main body of tube 34 only at its upper  
158 dimension, tab 50 is biased to remain positioned within the dimensions of the “wall” of tube  
159 34. If protrusion 56 is pushed outwardly, for example with contact with the adjustment tool  
160 30 as will be explained hereafter, tab 50 is biased to resist such displacement and to tend to  
161 move itself and protrusion 56 back to their original unstressed position.

162 In an alternate embodiment shown in FIG. 4a, the upper surface 40 of tube 34 has a  
163 series of indentations 58 located at certain locations around the upper surface 40. The  
164 purpose of these indentations 58 will be explained in more detail hereafter.

165 An index 59 may be placed on the upper surface 40 of tube 34. Index 59 visually  
166 indicates the settings of valve 10 when locator tool 26 is correctly oriented with valve 10.

167 In many adjustable valves, such as the valve 10 shown in US Pat. No. 5,637,083, the  
168 dome 18 of the valve 10 has a direction of orientation. For example, in the valve 10 shown  
169 in the '083 patent, the width "W" of the dome 18 is narrower transverse to the direction of  
170 fluid flow "A" than is the length "L" of the dome 18 along the direction of fluid flow "A" as  
171 shown in Figures 1 - 3. This difference in dimensions allows the dome 18 itself to have a

As described, in the preferred embodiment, the locator central opening 44 has a similar shape to the dome 18. In particular, the locator central opening 44 has an elongated shape that corresponds to the shape of the dome 18. Although this is the preferred shape of locator central opening 44, other shapes may also be used. For example, if dome 18 has a

194 different shape, cylindrical, circular, spherical, slot-shaped, diamond, triangular, rectangular  
195 or irregular, to name but a few of the many possible choices that will occur to those skilled  
196 in the art, locator central opening 44 would also have a corresponding shape. The key here  
197 is to have a shape for the locator central opening 44 that allows the locator tool 26 to be  
198 oriented to and aligned with the valve 10 in a precise predictable manner. Additionally, in  
199 the preferred embodiment, locator central opening 44 should allow the physician to palpate  
200 the implanted valve 10 through the locator central opening 44.

201 The indicator tool is shown in Figures 8 - 13 generally labeled 28. The indicator  
202 tool 28 indicates the current setting of the adjustable valve 10 and confirms new settings of  
203 the valve 10 after the new settings have been implemented.

204 Indicator tool 28 has two main parts: a indicator central indicator central body 60  
205 and a compass 62. Indicator central indicator central body 60 has an annular portion 64.  
206 Annular portion 64, in the preferred embodiment, is cylindrical with an outer diameter "E"  
207 that is slightly less than the inner diameter "D" of tube 34. An indicator lip 66 extends  
208 outward from the upper surface 68 of indicator central body 60. The outer diameter "F" of  
209 indicator lip 66 is larger than the inner diameter "D" of tube 34.

210 In the preferred embodiment corresponding to the embodiment of the locator tool 26  
211 having a slot 48 on the inner surface 38 of tube 34, central body 60 has a ridge 70 extending  
212 outward from its outer surface 72. Ridge 70 extends upward from the bottom 74 of the  
213 central body 60 at substantially a right angle to indicator lip 66. Ridge 70 is dimensioned to  
214 slide into slot 48 so that the interaction between slot 48 and ridge 70 will keep central body  
215 60 from rotating with respect to the locator tool 26 in use as will be described hereafter.

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234 In use, after the orientation of the valve 10 has been established by locator tool 26 as  
235 described above, the indicator central body 60 of indicator tool 28 is placed within tube 34  
236 of locator tool 26. Because the outer diameter "E" of the annular portion 64 of the indicator  
237 central body 60 is slightly smaller than and is conformal to the inner diameter of tube 34,

238 indicator central body 60 should pass into tube 34 until lip 56 contacts and rests upon the  
239 upper surface 40 of tube 34.

240 In the preferred embodiment, ridge 70 will align with and interact with slot 48 to  
241 precisely orient indicator tool 28 with locator tool 26. In the alternate embodiment,  
242 indicator lip 66 is rotated until protrusions 76 are in contact with the indentations 58 in  
243 locator tool 26. In either configuration, locator tool 26 and indicator tool 28 are aligned and  
244 oriented with respect to the preferred orientation of valve 10 (FIG. 20). Pointer 84 will then  
245 interact with the magnet 20 of valve 10 so that pointer 84 will align itself with the magnet  
246 20 of valve 10. This will cause pointer 84 to point to a spot on index 88. Where the pointer  
247 84 points to on index 88 indicates the position of the magnet 20 of the valve 10. The  
248 position of the magnet 20 indicates the setting of the valve 10.

249 The adjustment tool is shown in Figures 14 - 18 generally labeled 30 The  
250 adjustment tool 30 interacts magnetically with the implanted adjustable valve 10 to couple  
251 with the magnet 20 fixed to a movable internal element in valve 10 to change the setting of  
252 the valve 10..

253 Adjustment tool 30 has two main parts: an adjustment central body 90 and a magnet  
254 92. Magnet 92 performs the function of the external magnet 24 described above.

255 Adjustment central body 90 has an adjustment annular portion 94 made up of an outer wall  
256 96, an inner wall 98 and an upper wall 100. Adjustment annular portion 94 has an annular  
257 open area 102 between outer wall 96 and inner wall 98 and opposite upper wall 100. In the  
258 preferred embodiment, outer wall 96 is cylindrical with an outer diameter "G" that is  
259 slightly less than the inner diameter "D" of tube 34. An adjustment lip 104 extends outward

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from the upper edge 106 of adjustment central body 90. The outer diameter "H" of adjustment lip 104 is larger than the inner diameter "D" of tube 34. In the preferred embodiment, adjustment lip 104 is made of a clear material so that index 59 may be viewed through adjustment lip 104 when adjustment tool 30 is in place on locator tool 26.

Adjustment central body 90 has a series of indentations 108 near its bottom 110. These indentations 108 are located a distance from adjustment lip 104 and configured so that the indentations 108 will interact with protrusion 56 on tab 50 when adjustment tool 30 is mated to locator tool 26 as described below. Indentations 108 are spaced around the periphery of adjustment central body 90 corresponding to the location of the settings of the valve 10.

Magnet 92 is fixed in place in within adjustment central body 90. Magnet 92 has a north pole N and a south pole S aligned along an axis "J" of adjustment central body 90. Axis J is aligned with a direction indicator which is preferentially in the form of an arrow 112.

In use, the orientation of the valve 10 is first established by locator tool 26 and indicator tool 28 as described above. Then, the adjustment tool 30 is used, as necessary or as desired, to change the position of the magnet 20 and consequently the setting of the valve 10. This is done by first removing indicator tool 28 from locator tool 26. Then, adjustment tool 30 is positioned above locator tool 26 with the arrow 112 aligned with the pressure level setting on index 59 determined by the indicator tool 28 (FIG. 21). Maintaining this alignment, the adjustment tool 30 is lowered toward the locator tool 26 until the adjustment central body 90 enters tube 34 and adjustment lip 104 contacts the upper surface 26 of tube

284 In this position, magnet 92 couples with magnet 20 in valve 10. Adjustment central  
285 body 90 is then rotated so that the arrow 112 points to the desired setting of valve 10  
286 indicated on index 59. Because magnet 20 is magnetically coupled to magnet 92, as magnet  
287 92 rotates with adjustment central body 90, magnet 20 will also rotate and thereby move to  
288 the desired setting of valve 10. As central body 90 rotates, protrusion 56 will be moved out  
289 of contact with the indentation 108 corresponding to the last setting of the valve and move  
290 against the outer surface outer wall 96 of central body 90. When magnet 92 has moved to  
291 the next setting of the valve 10, protrusion 56 should contact the next indentation 108  
292 corresponding to the next setting of the valve 10. The user should feel the protrusion 56  
293 moving into or out of this indentation 108. In this way, the user has tactile confirmation  
294 that the adjustment tool 30 has moved to and is aligned with a new valve setting. This  
295 process may be repeated as desired until the adjustment tool 30 has moved the magnet 92,  
296 and correspondingly the magnet 20, to the new ultimate valve setting.

297 After the magnet 20 of valve 10 has been moved to a new setting, indicator tool 28  
298 should be used again as described above to confirm that magnet 20 is in the desired position  
299 and that, therefore, valve 10 is at the desired valve setting.

300 In the described preferred embodiment, locator tool 26 is mechanically coupled to  
301 either indicator tool 28 or adjustment tool 30 through the interaction of tube 34 and either  
302 indicator central body 60 or adjustment central body 90, respectively. In this embodiment,  
303 the hollow cylinder formed by tube 34 “captures” the cylindrical bodies of indicator central

Alternately, with respect to the interaction between the locator tool 26 and the indicator tool 28, instead to the inner surface 38 of tube 34 and indicator central body 60 both being conformally cylindrical, the inner surface 38 and indicator central body 60 may have other conformal shapes that allow the two tools to be mated together and maintain a desired orientation. For example, the inner surface 38 of tube 34 may be square, rectangular, hexagonal, elliptic or any other shape. Indicator central body 60 would also have a corresponding conformal shape. In this way, when indicator tool 28 is mated with locator tool 26, indicator tool 28 would be precisely located and oriented with respect to locator tool 26. Other means may occur to those skilled in the art.

320 All such means for mechanically coupling the locator tool 26 to either indicator  
321 central indicator central body 60 or adjustment central body 90 are intended to be within the  
322 scope of the invention. The key function of such mechanical coupling means is to ensure  
323 that the indicator central indicator central body 60 or adjustment central body 90 are aligned  
324 with the locator tool 26. Further, whatever the design, it is a key function of the mechanical  
325 coupling means to ensure that the magnet 92 of the adjustment central body 90 is allowed to



Further, the interaction of slot 48 or protrusions 76 on tube 34 with ridge 70 or indentations 58 of indicator tool 28, respectively, helps to align the indicator tool 28 with the locator tool 26. Although this is the preferred method of aligning these tools, other ways of aligning the tools will occur to those skilled in the art in addition to the means for mechanically coupling locator tool 26 to indicator tool 28 described above, which provides an alignment of the locator tool 26 and indicator tool 28. These additional means include, but are not limited to, reversing the placement of the slots and ridges or protrusions and detents on the respective tools. In addition, other means of mechanical alignment will occur to those skilled in the art.

337 Further, another aid in aligning the locator tool 26 and the indicator tool 28 include  
338 visual indicators of position on the respective devices. Examples of these visual means to  
339 aid in aligning the respective tools include, but are not limited to aligning indicator marks,  
340 line, templates or the like on the respective devices.

In addition, locator tool 26 has been described in the preferred embodiment having a locator central opening 44 to allow the physician to palpate the valve 10 through the locator central opening 44. Although this is the preferred embodiment, locator tool 26 may also not have a locator central opening 44. In this embodiment, the physician would align the locator tool 26 with the valve 10 by other means. One such means could be determining the orientation of the valve 10 by palpating the valve 10 and then noting the direction of

365 Although a particular embodiment of the invention has been described in detail  
366 herein, it is to be understood that the description has been given for the purpose of  
367 illustrating the invention and not for limiting the invention to the embodiment specifically  
368 described. Various modifications or changes will occur to those skilled in the art. These

369 changes or modifications may be made without departing from the spirit and scope of the  
370 invention. Accordingly, the invention is not to be limited, except as by the scope of the  
371 appended claims.